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10/583,840	03/30/2007	Young Ha Rhee	CMT-0072	4646
23413	7590	04/28/2009	EXAMINER	
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			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/583,840	Applicant(s) RHEE ET AL.	
	Examiner ALEXANDER D. KIM	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,9 and 15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,9 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>09/21/2006,06/22/2006</u> | 6) <input checked="" type="checkbox"/> Other: <u>Notice to Comply</u> |

DETAILED ACTION

Application Status

1. By virtue of a preliminary amendment filed on 02/04/2009, claims 7-8, 10-14 and 16-19 have been canceled; and claims 1-6, 9 and 15 have been amended.

Claims 1-6, 9 and 15 are pending in this instant case.

Election

2. Applicant's election of Group II, Claims 1-6, 9 and 15, is acknowledged. Because applicant did not distinctly and specifically point out the status of traverse in the restriction requirement, the election has been treated as an election without traverse (M.P.E.P. § 818.03(a)).

Claims 1-6, 9 and 15 will be examined herein.

Priority

3. The instant application is a 371 filing of the International Application No. PCT/KR05/04439 filed on 12/22/2005. The Examiner notes that the requirements of national stage entry of the instant application had been completed (note assigned U.S. filing date) within 30 months of the earliest claimed priority date; the related international application includes both a search report and a preliminary examination report.

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d) to a foreign patent application 10-2005-0059907 (Republic of Korea).

Information Disclosure Statement

4. The information disclosure statements (IDSs) filed on 09/21/2006 and 06/22/2006 has been reviewed, and its references have been considered. A copy of Form PTO/SB/08 is attached to the instant Office action.

Compliance with Sequence Rules

5. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. §1.821(a)(1) and (a)(2). However, this application fails to fully comply with the requirements of 37 C.F.R. 1.821 through 1.825; Applicants' attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990).

Figure 5 discloses one nucleic acid sequence and three polypeptide sequences. Labeling using a SEQ ID NO for each sequence must be inserted into the brief description of the drawings or into the Figure directly.

If the noted sequences are in the sequence listing as filed, Applicants must amend the specification to identify the sequences appropriately by SEQ ID NO. If the noted sequences are not in the sequence listing as filed, Applicants must provide (1) a substitute copy of the sequence listing in both computer readable form (CRF) and paper copy, (2) an amendment directing its entry into the specification, (3) a statement that the content of the paper and CRF copies are the same and, where applicable, include no new matter as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.821(b) or

1.825(d), and (4) any amendment to the specification to identify the sequences appropriately by SEQ ID NO.

Objections to the Specification

6. The specification is objected to because of the following informalities:

The abstract of the disclosure is objected to because it contains multiple paragraphs. It should have one paragraph. Correction is required. See MPEP § 608.01(b).

Claim Objections

7. Claims 1-6, 9 and 15 are objected to because of the following informalities:

(a) Claim 1 (Claims 2-6, 9 and 15 dependent therefrom) recites "PHA". The use of abbreviation PHA should be spelled out on a first appearance in claims.

(b) Claim 5 recites "molecular weight of the copolymer" without a unit. Appropriate unit should be used after recitation of "several millions" and also provide support for the unit.

(c) Claim 15 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In the instant case, the independent claim 1 recite using the *Pseudomonas sp.* HJ-2 with deposit number of KCTC 0406 BP, whereas the method of Claim 15

encompasses culturing any microorganism transformed with a short-chain-length PHA synthetic gene of a *Pseudomonas* sp. HJ-2 strain, which is broader than the independent Claim 1.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-6, 9 and 15 are rejected under of 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 (Claims 2-6, 9 and 15 dependent therefrom) provides for the use of microorganisms, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claim 1-6, 9 and 15 are rejected under 35 U.S.C. 112, first paragraph, **enabling deposit**, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ novel biological material, specifically the *Pseudomonas sp.* HJ-2 strain deposited as KCTC 0406 BP. Since the biological material are essential to such an invention they must be obtainable by a repeatable method set forth in the specification or otherwise readily available to the public. However, the specification does not show that this strain is readily available to the public. If the biological materials are not so obtainable or available, the requirements of 35 USC 112 §1st may be satisfied by a deposit of the biological materials.

The specification does not disclose that applicants have deposited the biological materials according to the Budapest Treaty. Also, the following requirement has to be satisfied: An affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific of record over his or her signature and registration number, stating that the specific biological materials will be irrevocable and without restriction or condition released to the public upon the issuance of a patent, the name and address of the depository in the specification would satisfy the deposit requirement made herein.

Applicant's attentions is directed to MPEP section 2400 in general, and specifically to 2411.05, as well as to 37 CFR 1.809(d), wherein it is et forth that "the

specification shall contain the accession number for the deposit, the date of the deposit, “the name and address of the depository, and a description of the deposited material sufficient to specifically identify it and to permit examination”. The specification should be amended to include this information, however, applicant is cautioned to avoid entry of new matter into the specification by adding any other information.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. Claims 1-6, 9 and 15 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

19. Claims 1-6 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Kim et al. (Korean Patent 10-1999-0080695, Published 15 Nov. 1999, as cited in the IDS).

Claims 1-6 and 9 are drawn to a method for preparing a PHA block copolymer comprises a plurality of 3HB and a plurality of 3HV by biosynthesis using microorganisms *Pseudomonas* sp. HJ-2 strain deposited as KCTC 0406 BP as disclosed in claims 1-6 and 9.

Kim et al. teach a method of preparing Poly-3-hydroxyalkanoate (PHA) block copolymer having rubber-elasticity (which is biodegradable elastic material, see Abstract and the Title) using microorganisms "*Pseudomonas* sp. HJ-2 strain deposited as KCTC 0406 BP" (see page 4, lines 11-12 or Abstract) for preparing a PHA block copolymer comprises 5-100% of a plurality of 3HB (Formula 1), 0-95% a plurality of 3HV (Formula 2) and 0-80% a plurality of copolymer Formula 3 (see chemicals in the middle of page 4; and line 15 for the recitation of %); thus, meeting the limitations in Claims 1, 4 and 6. Kim et al. teach the produced PHA block copolymer would be pressed with 10 to 50 tons after heating to about 150 °C to make permanently shaped film (see page 7, lines 37-38); thus, meeting the limitation of Claim 2. Kim et al. teach the produced PHA block copolymer would be used to make rubber band, for example on page 7 line 9, which would recover its original state of originally shaped material when it is released from a stretched shape (i.e., temporarily shaped) since its melting point is about 40-60

°C (see bottom of page 2 and bottom of page 3); thus, meeting the limitation of Claim 3. Kim et al. teaches a method of preparing copolymer from the heptanoic acid (see Example 3, bottom of page 11); thus, meeting the limitation of Claim 9.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

24. Claim 1-6, 9 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (Korean Patent 10-1999-0080695, Published 15 Nov. 1999, as cited in the IDS) in view of Timm et al. (Appl Microbiol Biotechnology, 1994, Vol. 40, pages 669-675) as evidenced by Daniel et al. (Current Microbiology, E publication June 13, 2005, Vol. 50, pages 329-333).

Kim et al. teach a method of preparing Poly-3-hydroxyalkanoate (PHA) block copolymer having rubber-elasticity (which is biodegradable elastic material, see Abstract and the Title) using microorganisms "*Pseudomonas* sp. HJ-2 strain deposited as KCTC 0406 BP" (see page 4, lines 11-12 or Abstract) for preparing a PHA block copolymer comprises 5-100% of a plurality of 3HB (Formula 1), 0-95% a plurality of 3HV (Formula 2) and 0-80% a plurality of copolymer Formula 3 (see chemicals in the middle of page 4; and line 15 for the recitation of %); thus, meeting the limitations in Claims 1, 4

and 6. Kim et al. teach the produced PHA block copolymer would be pressed with 10 to 50 tons after heating to about 150 °C to make permanently shaped film (see page 7, lines 37-38); thus, meeting the limitation of Claim 2. Kim et al. teach the produced PHA block copolymer would be used to make rubber band, for example on page 7 line 9, which would recover its original state of originally shaped material when it is released from a stretched shape (i.e., temporarily shaped) since its melting point is about 40-60 °C (see bottom of page 2 and bottom of page 3); thus, meeting the limitation of Claim 3. Kim et al. teaches a method of preparing copolymer from the heptanoic acid (see Example 3, bottom of page 11); thus, meeting the limitation of Claim 9.

Kim et al. also teach using *Pseudomonas* sp. HJ-2 for making C4 to C14 chain length PHAs (see page 4, line 9); wherein C4 chain length meets the limitation of short-chain-length PHA in Claim 15.

Kim et al. do not teach a method of culturing a microorganism transformed with a PHA synthetic gene of a *Pseudomonas* sp. HJ-2 strain which belongs to Class I PHA synthases [see Abstract lines 8-9 of Daniel et al. (who also teach the PHA synthase of *Pseudomonas* sp. HJ-2 in "GenBank AAQ27537", see middle of right column on page 331)].

Timm et al. teach a process of a general method for identification of polyhydroxyalkanoic acid synthase genes from pseudomonads belonging to the rRNA homology group I; and teach a method of producing PHA by recombinant strain (prepared by transformation procedure as disclosed on page 670, top of right column) of *Pseudomonas* sp. as shown in Table 2 on page 672.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to clone and transform with an overexpression vector having the PHA synthase genes from the *Pseudomonas* sp. HJ-2 of Kim et al. to a microorganism with a reasonable expectation of success because overexpression of genes which encodes an enzyme is well known for one skilled in the art for increasing a product yield (e.g. PHA) by the increase of the corresponding enzyme. The motivation to do so is provided by Kim et al. who teach the usefulness of PHA in "agriculture, daily necessities, medical supplies, grocery packing and the field of medical science" (see Abstract); thus, increasing the PHA production is advantageous in manufacturing a product using PHA. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEXANDER D. KIM whose telephone number is (571)272-5266. The examiner can normally be reached on 11AM-7:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alexander D Kim/
Examiner, Art Unit 1656

/Rebecca E. Prouty/
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